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FORMULATION DEVELOPMENT AND EVALUATION OF NOVEL DUAL-COMPARTMENT CAPSULE FOR STOMACH SPECIFIC DRUG DELIVERY

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ABSTRACT

The aim of the proposed research work was to develop a unique dual-compartment capsule dosage form of ciprofloxacin hydrochloride (CHL) which is well-known to have short elimination half-life and narrow absorption window. Formulated dual-compartment capsules were evaluated for its suitability for stomach specific drug delivery by employing different polymers such as Guar gum, Xanthan gum. Formulations were assessed for interaction studies, in vitro buoyancy, effect of polymer concentration on drug release and release kinetics. Experimental results demonstrated that natural polymers can be effectively exercised to formulate capsule dosage form for improved gastro retention and sustained drug release; which may be better and economic alternative for synthetic polymers.

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INTRODUCTION:

The real challenge in the development of an oral controlled-release drug delivery system is not just to sustain the drug release but also to prolong the presence of the dosage form within the gastrointestinal tract (GIT) until all the drug is completely released at the desired period of time[1]. Floating systems are of two types: (A) effervescent systems, depending on the generation of carbon dioxide gas upon contact with gastric fluids and (B) non-effervescent systems. Ring Cap, a patented technology could be an example of such development. The intent of such technology was to provide a delivery system with reliable and reproducible drug release characteristics[2]. CHL is a broad-spectrum antibiotic that is active against both gram-positive and gram-negative bacteria. It functions by inhibiting DNA gyrase, a type II topoisomerase, which is an enzyme necessary to separate replicated DNA, thereby inhibiting cell division. It is rapidly absorbed orally and shows 60-70% oral bioavailability and 3- 4 hours elimination half-life[3]. The use of naturally occurring biocompatible polymeric materials has been the focus of recent research activity in the design of dosage forms for oral controlled release administration. Gums from natural sources hydrate and swell on contact with water and these have been used for the preparation of single unit dosage forms. Xanthan gum offers potential utility as a drug carrier because of its inertness and biocompatibility. It is used as an effective excipients for sustained release formulations. Guar gum is used in solid dosage forms as a binder, disintegrant, and as a polymer in the floating drug delivery system. Karaya gum is a partially acetylated polymer of galactose, rhamnose, and glucuronic acid. The intention of purposed investigation was to develop a floating ring cap delivery system in cross-linked hard gelatin capsule shell by employing natural polymers and to assess their effectiveness as a better and economic alternative for synthetic polymers in form of floating ring capsule for enhanced gastroretention and sustained drug release[4].

MATERIALS AND METHODS

Ciprofloxacin hydrochloride was supplied as a generous gift sample from Ajanta Pharmaceuticals Ltd. (Jalgaon, India). Xanthan gum and Eudragit® S 100 was purchased from Research Lab, Fine Chemicals Ltd. (Mumbai, India). Guar gum and Karaya gum, HPMC K15M was purchased from Loba Chem. Pvt. Ltd., (Mumbai, India). All other chemicals and reagents used were of analytical grade.

Preparation of separating ring cap band:

Separating ring cap band was prepared by film casting method; the method employed 2% HPMC solution in

water, followed by the addition of 5% glycerol. Formed mixture was poured into petri dish and was allowed to dry at 45 °C. The dried film was cut uniformly into circular rings with punch, each having 1 mm thickness and 5.1 mm in diameter[4]

Preparation of enteric gelatin body

Enteric gelatin bodies were prepared by dipping method. Hard gelatin body portion of capsule was separated from the cap and dipped in coating solution. Coating solution was made by dissolving the Eudragit S 100 in acetone. Coated capsule were air-dried overnight for complete removal of organic solvent.

Preparation of new floating ring capsules:

Enteric coated gelatin body of capsule was filled with 50 mg powder Xanthan gum at bottom and separating ring band placed over it manually, then physically blended 250 mg of CHL with natural polymers like guar gum, xanthan gum and karaya gum (Table I) in different weight proportion were filled into hard gelatin capsule (# 0.), Finally enteric coated capsule body was sealed with hard gelatin cap Figure.1

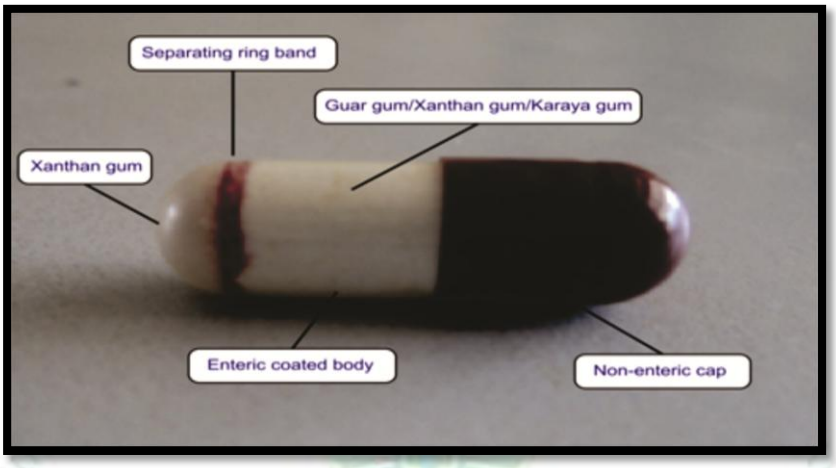

Figure 1: An image showing assembly of floating ring capsule

Table I: Formulations of floating capsules

Formulation code	Drug (mg)	Guar gum (mg)	Xanthan gum (mg)	Karaya gum (mg)
F1	250	5	-	-
F2	250	10	-	-
F3	250	20	-	-
F4	250	30	-	-
F5	250	40	-	-
F6	250	50	-	-
F7	250	80	-	-
F8	250	-	10	-
F9	250	-	20	-
F10	250	-	30	-
F11	250	-	40	-
F12	250	-	50	-
F13	250	-	80	-
F14	250	-	-	20
F15	250	-	-	30
F16	250	-	-	40
F17	250	-	-	50
F18	250	-	-	60
F19	250	-	-	70
F20	250	-	-	80
F21	250	-	-	90
F22	250	-	-	100

Evaluation of dual-compartment capsules formulations

Weight uniformity: 20 capsules were weighed individually and the average weight was determined. Test was performed according to the official method.

Drug content: The Ciprofloxacin ring capsules of each formulation were dissolved in 0.1 N HCl, then prepared solution was used for determination of Ciprofloxacin hydrochloride content by using a UV-spectrophotometer.

In vitro buoyancy study: In vitro buoyancy was studied by determining floating time of capsules in 0.1 N HCl. The duration of buoyancy was determined in 0.1 N SGF (Simulated gastric fluid) as a medium by using the USP type II dissolution apparatus at 50 rpm and temperature was maintained at 37±5°C. The floating duration of all capsules was measured by visual observation (USP).

***In vitro* drug release studies:** *In vitro* drug release study was carried in USP (paddle) dissolution apparatus at 50 rpm and temperature maintained at 37 ± 1°C.

RESULTS AND DISCUSSION:

Weight uniformity: The results of weight uniformity of formulation F1, F12 and F22 are shown in Table 2. All these developed formulations met the I.P specifications for weight uniformity.

Drug content: The percent drug content within these developed capsules was determined and this was within the range between 98.18 ± 1.02 to 98.94 ± 1.29 % (Table III). This finding confirms uniform mixing of CHL with other formulation ingredients.

Table 2: Weight uniformity and percent drug content results of ciprofloxacin hydrochloride capsules

Formulation Code	Weight Uniformity	Drug Content(%) ± S.D*
	Mean weight ± S.D.* (mg)	
F1	308.34 ± 2.54	98.18 ± 1.02
F12	349.73 ± 7.47	99.68 ± 1.00
F22	401.14 ± 6.88	98.94 ± 1.29

***In vitro* buoyancy study:** The air entrapped in dense powder during filling operation of capsules aids for the buoyancy phenomena. They were floated well without floating lag time. The floating time of these floating ring capsules was more than 8 hours. This may be accounted due to increased gel strength of the polymeric combination matrices with drug.

***In vitro* drug release studies:**

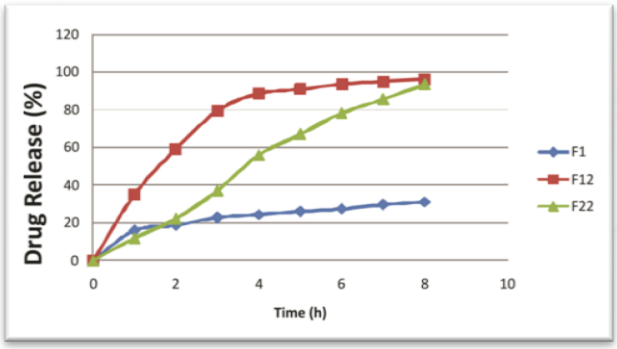

Figure 2: Comparison of *in vitro* release between formulations F1, F12, and F22.

The drug release from floating capsules was found to be 15.64 to 30.95 % for F1 to F7 with Guar gum. The drug release from formulations F8 to F13 varied between 27.55 to 81.08% for Xanthan gum and F14 to F22 varied between 26.93 to 93.53% for Karaya gum. It was observed that the type of natural gum influences the drug release pattern. Varying the amount of guar gum, xanthan gum, and karaya gum affect the drug release. Formulations F1, F12 and F22 showed prolonged drug release for more than 8 hours emerging as best formulations.

CONCLUSION

In the present study ciprofloxacin hydrochloride floating ring capsule using natural gums like guar gum, xanthan gum and karaya gum were developed. The type of polymer affects the drug release rate and the mechanism. Formulation F12 showed sustained drug release for 8 hours so it was selected as the best formulation among all the formulation. The Kinetics of drug release was best explained by first order equation. The results of current study clearly indicate a promising potential of these floating ring capsules containing ciprofloxacin hydrochloride as an improved alternative to for gastroretentive sustained release dosage forms.

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